

### REMARKS

Applicants request favorable reconsideration of this application in view of the foregoing amendments and the following remarks. Of claims 1-25 which are pending in the application: (a) claims 6, 7, 9-12, 15-18, 20, and 23-25 remain withdrawn; and (b) claims 1-5 and 8 were rejected in the Office Action. Applicants appreciate the allowance of claims 14, 19, 21, and 22 and the indication of allowable subject matter in claims 3-5. Applicants have amended pending claims 1, 3, and 4 and withdrawn claim 7 without presenting new matter. Accordingly, claims 1-5, 8, 13, 14, 19, 21, and 22 are respectfully resubmitted for further consideration.

In response to the positive indication of allowable subject matter in claims 3-5, claims 3 and 4 have been amended to be in independent claim format. In addition, claim 4 has also been broadened by replacing a recitation of "or" with "and/or."

With respect to claim 13, Applicants note that it was neither rejected nor allowed. Accordingly, as claim 13 has not been amended, Applicants expect that the next Office Action will be made **non-final**.

#### 1. **Drawings**

Applicants respectfully request that the Examiner approve the changes made to Figure 1 in the Amendment filed with the Request for Continued Examination ("RCE") on February 26, 2004.

#### 2. **Rejection of Claims 3 and 4 under 35 U.S.C. § 112, ¶ 2**

The Examiner rejected claims 3 and 4 under 35 U.S.C. § 112, ¶ 2 as allegedly "being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention." Presumably, the Examiner intended to extend this rejection to claim 5 (which depends from claim 4 and, therefore, recites all of the rejected limitations of claim 4), particularly as claim 5 was indicated as being rejected in the Office Action Summary but was not rejected in the Detailed Action portion of the Office Action.

With respect to claim 3, the Examiner stated: "it is unclear how one can have a closed pocket when there is an intermediate space established between said upper and lower opposing faces where the plug and housing do not contact each other." With respect to claim 4, the Examiner stated: "it is unclear how the plug and the housing contact each other at upper and lower opposing faces, that there is a closed pocket provided by a cavity or recess formed in the plug or housing and the cavity or recess positioned between the upper and

lower opposing faces.” For the following reasons, claims 3 and 4 particularly point-out and distinctly claim subject matter pertaining to what Applicant regards as the invention.

Preliminarily, Applicants note that the Examiner made a similar rejection in the Office Action mailed May 31, 2002 and that the rejection was successfully traversed in the Amendment filed December 2, 2002 (as acknowledged in the Office Action mailed February 4, 2003). Applicants note that the rejection was traversed by relying on non-elected embodiments shown in Figures 2 and 3. However, as claims 3 and 4 read on the elected embodiment shown in Figures 16 and 17, the rejection remains traversable as hereafter explained in detail with reference to those figures.

The previously dependent limitations of claim 3 to which the Examiner objected were (explanatory numbers added):

wherein [1] the plug and the housing contact each other at upper and lower opposing faces thereof, and [2] the closed pocket is provided by an intermediate space established between said upper and lower opposing faces where said plug and housing do not contact each other.

Similarly, the previously dependent limitations of claim 4 to which the Examiner objected have been amended as follows (explanatory numbers added):

wherein [1] the plug and the housing contact each other at upper and lower opposing faces thereof, and further wherein [3] the closed pocket is provided by a cavity or recess formed in the ~~plug or~~ plug and/or housing, and [4] said cavity or recess is positioned between said upper and lower opposing faces.

**Limitation [1]:** As can be readily seen, claims 3 and 4 both recite: “[1] the plug and the housing contact each other at upper and lower opposing faces thereof.” Accordingly, the following explanation of this limitation is applicable to both claims. As shown in Figure 16, a face of the upper side of the plug 79 contacts an opposing face of the second capsule housing part (*i.e.*, upper part) 78B of the capsule housing 78. Further, a face of the lower side of the plug 79 contacts an opposing face of the first capsule housing part (*i.e.*, lower part) 78A of the capsule housing 78. Accordingly, as recited in claims 3 and 4, “the plug and the housing contact each other at upper and lower opposing faces thereof.” Therefore, limitation [1] is sufficiently definite.

**Limitations [2] and [3]:** An annular, closed pocket 84 is defined by the first and second capsule housing parts 78A, 78B and the plug 79. Specifically, the first and second capsule housing parts 78A, 78B form the upper and outer sides of the pocket 84 and the plug 79 forms the inner side of the pocket 84. Correspondingly, this annular pocket 84 is not drawn with any cross-hatching in Figure 16. Moreover, as clearly shown in Figure 16, in this region there are intermediate portions of the plug 79 and the capsule housing 78 which are

not in contact with each other. Accordingly, as recited in claim 3, “[2] the closed pocket is provided by an intermediate space established between said upper and lower opposing faces where said plug and housing do not contact each other.” Further, as recited in claim 4, “[3] the closed pocket is provided by a cavity or recess formed in the plug and/or housing.” Therefore, limitations [2] and [3] are sufficiently definite.

**Limitation [4]:** Finally, with respect to limitation [4], Applicant notes that the pocket 84 is formed between (a) the upper opposing faces of the capsule housing 78 (*i.e.*, second capsule housing part 78B) and the plug 79 and (b) the lower opposing faces of the capsule housing 78 (*i.e.*, first capsule housing part 78A) and the plug 79. Accordingly, as recited in claim 4, “[4] said cavity or recess is positioned between said upper and lower opposing faces.” Therefore, limitation [4] is sufficiently definite.

As Applicants have clearly shown that limitations [1]-[4] are definite, it should be readily apparent that claims 3 and 4 fully satisfy the requirements of 35 U.S.C. § 112, ¶ 2. Therefore, for at least these reasons, the rejection of claims 3 and 4 under § 112, ¶ 2 should be withdrawn.

### **3. Rejection of Claims 1, 2, and 8**

The Examiner rejected claims 1, 2, and 8 under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 2,636,493 (“Lockhart”). For the following reasons, Applicants respectfully traverse this rejection.

As amended, claim 1 recites a capsule adapted for containing a dose of a therapeutic agent to be delivered within a pressurized fluid flow. The capsule includes, among other possible things (*italic emphasis added*):

a first member and  
a second member,  
wherein said first and second members are coupled together to provide a closed pocket within the members for containing the dose, and *one of said first and second members is moveable relative to the other member when an external portion of said capsule is contacted with a pressurized fluid flow, said first and second members being constructed and arranged such that upon said relative movement a passage is formed through said capsule and said pocket is opened to expose the dose for entrainment in fluid flowing through said passage.*

As hereafter explained in detail, Lockhart fails to teach or suggest such a capsule.

In making the rejection, the Examiner analogizes the tube section 11 to the “first member” and the head 16 to the “second member.” Multiple problems exist with these analogies.

First, whereas claim 1 recites that the first and second members are “moveable relative” to each other, the head 16 and the tube section 11 are fixed with respect to each other.

Second, whereas claim 1 recites that the first and second member “provide a closed pocket within” themselves, the tube section 11 and the head 16 do not “provide a closed pocket” within themselves for containing the dose. Rather, the combination of the tube section 11, the head 16, and the plug 18 provide the closed pocket (*i.e.*, liquid chamber 12).

Third, claim 1 recites that “upon said relative movement a passage is formed *through* said capsule[.]” By way of contrast, however, upon movement of plug 18 in the Lockhart device, a passage is not formed *through* the capsule. Rather, the bottom end 19 remains fully sealed from the outside environment. In the present invention, the passage being formed through the capsule is important because the pressurized gas must be able to enter the capsule, entrain the particles, and leave the capsule via a different passage from that used to enter the capsule.

Accordingly, for these reasons alone, the Examiner’s current rejection must be withdrawn. However, assuming, *arguendo*, that the Examiner intended to analogize the plug 18 to the “first member” and the combination of the tube section 11 and the head 16 to the “second member” (because the plug 18 is moveable relative to the tube section 11/head 16 and because the combination of the plug 18 and the tube section 11/head 16 defines a closed pocket, *i.e.*, liquid chamber 12), this analogy would also fail. Specifically, claim 1 recites that “one of said first and second members is moveable relative to the other member *when an external portion of said capsule* is contacted with a pressurized fluid flow.” By way of contrast, the *internal* side of the plug 28 in Lockhart is exposed to the pressurized fluid flow in the liquid chamber 12 when the tube section 11 is compressed. *See* Lockhart at col. 3, lines 69-75.

For at least the aforementioned reasons, Lockhart fails to teach or suggest each of the limitations of claim 1. Accordingly, Lockhart can not be used to reject claim 1, or any claim dependent thereon, under 35 U.S.C. § 102(b). Moreover, as claims 2 and 8 depend from claim 1, each of these dependent claims is also allowable over Lockhart, without regard to the other patentable limitations therein. As a result, Applicants respectfully request a withdrawal of the rejection of claims 1, 2, and 8 under § 102(b).

**4. Withdrawn Claims**

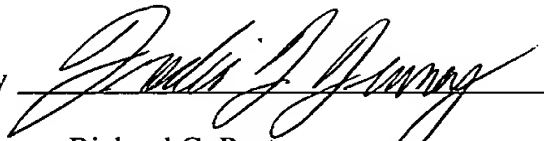
As withdrawn claims 9-12 depend from allowable claim 1, as withdrawn claims 6 and 7 depend from claim 4, and as withdrawn claims 15-18, 20, and 23-25 depend from allowed claim 14, each of these dependent, withdrawn claims is also allowable. Accordingly, when issuing a Notice of Allowance, the Examiner is requested, under 37 C.F.R. § 1.141 and M.P.E.P. § 809.04, to reenter and allow claims 6, 7, 9-12, 15-18, 20, and 23-25.

**CONCLUSION**

For the aforementioned reasons, claims 1-25 are now in condition for allowance. A Notice of Allowance at an early date is respectfully requested. The Examiner is invited to contact the undersigned if such communication would expedite the prosecution of the application.

Respectfully submitted,

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By 

Customer Number: 22428  
FOLEY & LARDNER LLP  
3000 K Street, N.W.  
Suite 500  
Washington, D.C. 20007-5143

Richard C. Peet  
Registration No. 35,792

Frederic T. Tenney  
Registration No. 47,131

Telephone: (202) 672-5300  
Facsimile: (202) 672-5399

Attorneys for Applicants

THE COMMISSIONER IS HEREBY AUTHORIZED TO CHARGE ANY ADDITIONAL FEES WHICH MAY BE REQUIRED REGARDING THIS APPLICATION UNDER 37 C.F.R. §§ 1.16-1.17, OR CREDIT ANY OVERPAYMENT, TO DEPOSIT ACCOUNT NO. 19-0741. SHOULD NO PROPER PAYMENT BE ENCLOSED HERewith, AS BY A CHECK BEING IN THE WRONG AMOUNT, UNSIGNED, POST-DATED, OTHERWISE IMPROPER OR INFORMAL OR EVEN ENTIRELY MISSING, THE COMMISSIONER IS AUTHORIZED TO CHARGE THE UNPAID AMOUNT TO DEPOSIT ACCOUNT NO. 19-0741. IF ANY EXTENSIONS OF TIME ARE NEEDED FOR TIMELY ACCEPTANCE OF PAPERS SUBMITTED HERewith, APPLICANT HEREBY PETITIONS FOR SUCH EXTENSION UNDER 37 C.F.R. § 1.136 AND AUTHORIZES PAYMENT OF ANY SUCH EXTENSIONS FEES TO DEPOSIT ACCOUNT NO. 19-0741.